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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,691	07/20/2001	Ping Gao	28341/00222.US1	9971

4743 7590 01/13/2003

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/909,691

Applicant(s)

GAO ET AL.

Examiner

Lakshmi S Channavajjala

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 and 28-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Receipt of supplemental IDS, dated 12-5-02; and request for extension of time and response to election requirement dated 11-18-02 is acknowledged.

#### ***Election/Restrictions***

Applicant's election without traverse of species of Group I in Paper No. 10 is acknowledged.

Claims 1-20 and 25-27 are readable on the elected species.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the following combination of references:

1. WO 96/03113 (WO '113) in view of US 5,866,159 to Hauer et al (hereafter Hauer)
2. Hauer in view of WO '113 or
4. Hauer in view of WO 99WO '848.

Instant claims are directed to a self-emulsifying drug delivery (SEDD) system comprising an extremely water-insoluble lipophilic active agent, a fatty acid, a surfactant and polyvinylpyrrolidone (PVP), wherein the weight ratio of fatty acid to PVP is 2:1 to 1:3.

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Dependent claims further limit the ratio of surfactant to PVP; recite specific surfactants, fatty acids, active agents etc.

WO '113 teaches a SEDD system for increasing bioavailability of water insoluble or oil soluble drugs, comprising the 0.1% to 17% drug, 2% to 50% of a solubilizer, 10% to 55% of an emulsifier and oil (claim 1 and pages 6-7, page 8, lines 14-24). Particularly, WO '113 teaches the claimed emulsifiers (page 7) and their solubilizers include fatty acids such as oleic acid, linoleic acid (lines bridging pages 7-8). WO '113 also teaches oral administration of their composition in the form of gelatin capsules (page 8, lines 25-28). WO does not teach PVP of the instant claims and also fails to teach specific drugs of claim 20.

Hauer teaches microemulsion concentrate compositions containing highly water insoluble drug such as cyclosporin, which is suitable for oral as well as topical administration (abstract, col. 3, lines 23-25). In addition to cyclosporin, the composition of Hauer further comprises surfactant (col. 9, lines 34 through col. 12, lines 34), a hydrophilic phase containing propylene glycol or tetrahydrofuryl ether of polyoxyalkanediol (col. 7), lipophilic phase comprising fatty acid triglycerides (col. 9) and a thickening agent (col. 12, lines 35-col. 13, lines 19). In particular, example 29 of Hauer recites claimed surfactants and PVP, with the ratios of surfactants to PVP being within the claimed limits.

WO '848 teaches self-emulsifying dosage forms of water-insoluble anticancer drugs such as paclitaxel, wherein the composition comprises a hydrophobic component comprising triglycerides, free fatty acids etc., surfactants, and hydrophilic components such as polyethylene glycol. The surfactants, fatty acids etc., described by WO '848 (pages 4-5 and example 5) read on the instant claimed components. WO '848 fails to teach PVP in their compositions.

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Thus, all the three references described above are directed to achieving increased bioavailability of highly water insoluble drugs and teach pre-concentrate of emulsion, which is the same as SEDD systems. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add PVP of Hauer, as a thickening agent, in the SEDD system of WO '113 or WO '848 because Hauer teaches that thickening agents such as PVP are capable of modifying the release characteristics of the lipophilic drug (col. 20, lines 53 through col. 21, lines 1-4). Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add fatty acids of WO '113 or WO '848 to the pre-emulsion concentrate of Hauer because WO '113 teaches fatty acids for solubilizing a substantially insoluble lipophilic drug, without any toxic side effects and WO '848 teach equivalence of fatty acids such as linoleic acid and triglycerides in the SEDD system for administering and improving bioavailability of lipophilic drugs. The above references do not teach the exact ratios of PVP and fatty acids. However, optimizing the ratios of individual components with their art recognized effect would have been within the gambit one of an ordinary skill in the art. Accordingly, a skilled artisan would have optimized the ratios of PVP and fatty acids as well as PVP and surfactants with an expectation to achieve the maximum desired bioavailability and a desired release pattern of a highly water-insoluble lipophilic drug.

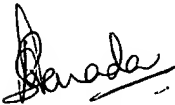
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615 January 10, 2003